This report is required by law (? USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject lo penalties as provided for in Section 2150

Set reverse side for additionalinformation

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Ilypsa, Inc

1. REGISTRATION NO. 93-R-0509 | Customer # 38104

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA inclucle Zip Code)

Ilypsa, Inc
5301 Patrick Henry Drive
Santa Clara, CA 95054

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

(b)(2)High, (b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Anima Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress. oi use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters				347	347
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11., Pigs					
12. Other Farm Animals					
13 Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility

2) Each principal investigator has considered alternatives to painful procedures.

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3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary **of all such exceptions is attached lo this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarianfor this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)

above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATI

(b)(6),(b)(7)(c)

or Print)

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DATE SIGNED

10/26/07

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Column E Explanation

1. Registration Number: 93-R-0509

2. {Number} 347 animals were used in this type of study.

3. {Species (common name)} hamsters were used in this type study.

4. Explain the procedure producing pain and/or distress.

   Hamsters are used as a model of *Clostrium difficile*-associated diarrhea (CDAD), which is a severe gastrointestinal disease in humans that may develop following antibiotic therapy. The potential for pain and/or distress results from the potential clinical signs of colitis and/or diarrhea that some animals (particularly untreated control animals) may experience after animals are treated with antibiotics and inoculated with *Clostridium difficile*.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.

   The prevention and/or abatement of clinical signs associated with CDAD (such as lethargy, diarrhea, etc.) are what is used to determine the efficacy of novel therapeutics for this disorder. If a novel therapeutic is efficacious, then clinical signs either do not develop or are eliminated. If a novel therapeutic is NOT efficacious, then animals may develop clinical signs. Therefore, it is not possible to eliminate these clinical signs as they used to screen for efficacy. Anesthetics, analgesics and tranquilizing agents would not treat the cause of this disease and would compromise the validity of the studies since their use would confuse interpretation of the results/clinical signs.

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